Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-30. (Canceled)

31. (Previously presented) A method of reducing or substantially completely eliminating irritation around the site of injection upon injection of a formulation containing propofol comprising: administering as a bolus intravenous injection or as an intravenous infusion at the injection site, a stable, sterile and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm consisting essentially of about 1% to about 15% of propofol, 1% up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing agent, and an aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier in a quantity sufficient to sufficient to render the final composition isotonic with blood, wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents.

32. (Previously presented) The method of claim 31, wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1.

33. (Previously presented) The method of claim 31, wherein the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5.

34. (Previously presented) The method of claim 31, wherein the dispersion has a viscosity of from about 1.5 to about 8 centipoise.

35. (Previously presented) The method of claim 31, wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1, and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the dispersion has a viscosity of from about 1.5 to about 8 centipoise.

36. (Previously presented) A method of inducing anesthesia or sedation comprising administering to a subject in need of same an anesthetic-inducing amount of a stable, sterile, and antimicrobial injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm consisting essentially of about 1% to about 15% of

propofol, 1% up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, and an aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier in a quantity sufficient to render the final composition isotonic with blood, wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents.

37. (Previously presented) The method of claim 36, wherein the ratio of propofol to diluent is about 1:4 to about 1:0:1.

38. (Previously presented) The method of claim 36, wherein the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5.

39. (Previously presented) The method of claim 36, wherein the dispersion has a viscosity of from about 1.5 to about 8 centipoise.

40. (Previously presented) The method of claim 36, wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1, and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the dispersion has a viscosity of from about 1.5 to about 8 centipoise.

41. (Previously presented) The method of claim 31 or 36, wherein the propofol-soluble diluent is selected from the group consisting of isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, squalane, alpha-tocopherol, triglycerides of medium chain fatty acids, and combinations thereof.

42. (Previously presented) The method of claim 31 or 36, wherein the propofol-soluble diluent is selected from the group consisting of pharmaceutically acceptable natural triglycerides from vegetable sources, pharmaceutically acceptable natural triglycerides from animal sources, pharmaceutically acceptable vegetable oils, omega-3 polyunsaturated fish oils, and combinations thereof.

43. (Previously presented) The method of claim 31 or 36, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of 1 ,2-dimyristoyl-sn-glycero-3-phosphocholine, 1,2-dimyristoyl-sn-glycero-3-[phospho-rac-(1 -glycerol)], egg lecithin, egg

phosphatidylcholine, soy phosphatidylcholine, saturated soy phosphatidylcholine, soy lecithin, dimyristoylphosphatidylcholine, dimyristoylphosphatidylglycerol, hydrogenated lecithin, and combinations thereof.

44. (Previously presented) The method of claim 31 or 36, wherein the tonicity modifier is selected from the group consisting of sucrose, dextrose, trehalose, mannitol, lactose, glycerol, and combinations thereof.

45. (Previously presented) The method of claim 31 or 36, wherein the dispersion is suitable for intravenous injection.

46. (Previously presented) The method of claim 31 or 36, wherein propofol is present in an amount of about 2% by weight of the dispersion.

47. (Previously presented) The method of claim 31 or 36, wherein the propofol-soluble diluent is a triglyceride of medium chain fatty acids.

48. (Previously presented) The method of claim 31 or 36, wherein the polyhydroxy tonicity modifier is mannitol.

49. (Previously presented) The method of claim 31 or 36, wherein the propofol concentration is about 2%, the propofol-soluble diluent is a triglyceride of medium chain fatty acids, the polyhydroxy tonicity modifier is mannitol, and the surface stabilizing amphiphilic agent is egg lecithin.

50. (Previously presented) The method of claim 31 or 36, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.

51. (Previously presented) The method of claim 31 or 36, wherein the polyhydroxy additive is present in an amount of about 2.5% to about 20% by weight of the dispersion.

52. (Previously presented) The method of claim 48, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.

53. (Previously presented) The method of claim 31 or 36, wherein the propofol-soluble diluent is a mixture of medium-chain triglycerides.

54. (Previously presented) The method of claim 53, wherein the triglyceride is a triglyceride of medium-chain fatty acids of synthetic or natural origin.

55. (Previously presented) The method of claim 53, wherein the triglyceride is present in an amount of 2% to 6% by weight of the dispersion.

56. (Previously presented) The method of claim 47, wherein the triglyceride is a triglyceride of medium-chain fatty acids of synthetic or natural origin.

57. (Previously presented) The method of claim 47, wherein the triglyceride is present in an amount of 2% to 6% by weight of the dispersion.

58. (Previously presented) The method of claim 47, wherein the triglyceride is present in an amount of 2% to 4% by weight of the dispersion.

59. (Previously presented) The method of claim 58, wherein the triglyceride is present in an amount of 4% by weight of the dispersion.

60. (Previously presented) The method of claim 53, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.

61. (Previously presented) The method of claim 31 or 36, wherein the amphiphilic agent is egg lecithin.

62. (Previously presented) The method of claim 61, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.

63. (Previously presented) The method of claim 62, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.

64. (Previously presented) The method of claim 31 or 36, which includes dimyristoylphosphatidyl glycerol.

65. (Previously presented) The method of claim 64, wherein the dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

66. (Previously presented) The method of claim 65, wherein the dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

67. (Previously presented) The method of claim 36, which includes egg lecithin and dimyristoylphosphatidyl glycerol.

68. (Previously presented) The method of claim 67, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion and the dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

69. (Previously presented) The method of claim 68, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion and the dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

70. (Previously presented) The method of claim 36, wherein the pH of the composition is about 4 to about 9.

71. (Previously presented) The method of claim 36, wherein the pH of the composition is about 5 to about 8.

72. (Previously presented) The method of claim 31 or 36, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

73. (Previously presented) The method of claim 31 or 36, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

74. (Previously presented) The method of claim 72, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

75. (Previously presented) The method according to claim 31 or 36, wherein the dispersion is steam sterilizable.

76. (Currently amended) A method of inducing anesthesia or sedation, comprising administering to a subject in need of same an anesthetic-inducing amount of a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) between about 1% to about 15% of propofol;

(b) between about 1% to about 8% of a propofol-soluble diluent;

(c) between about 0.5% to about 5% of a surface stabilizing amphiphilic agent; ~~and~~

(d) a pharmaceutically acceptable water-soluble polyhydroxy additive that acts as a tonicity modifier in the dispersion's aqueous phase; and

(e) water;

(f) provided the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of from about 0.8 to about 15 centipoise,

wherein the dispersion

prevents microbial growth, defined as no more than 0.5 log increase from the initial inoculum, of each of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans,* and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of each of said ~~organism~~ organisms is added to a separate aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range of 20-25°C, whereafter said aliquots are incubated at 20-25°C and are tested for viability of the microorganisms in the inoculated dispersion as determined by counting the colonies of said organism after 24, 48 hours and 7 days; and

results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.

77. (Previously presented) The method of claim 76, wherein the surface stabilizing amphiphilic agent is a surface modifier selected from the group consisting of ionizable

phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

78. (Previously presented) The method of claim 76, wherein the propofol-soluble diluent is selected from the group consisting of a synthetic fatty acid triglyceride, a natural fatty acid triglyceride, and mixtures thereof.

79. (Previously presented) The method of claim 76, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:3 to about 1:0.5.

80. (Previously presented) The method of claim 76, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:2 to about 1:1.

81. (Previously presented) The method of claim 76, wherein the propofol-soluble diluent is a mixture of medium-chain triglyceride and vegetable oil.

82. (Previously presented) The method of claim 81, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

83. (Previously presented) The method of claim 76, wherein the composition contains about 2% to about 10% of propofol.

84. (Previously presented) The method of claim 76, wherein the pharmaceutically acceptable water-soluble polyhydroxy additive provides the propofol-containing dispersion or composition with an osmolality of about 250 to about 700 milliosmolal.

85. (Previously presented) The method of claim 84, wherein the osmolality is about 300 to about 500 milliosmolal.

86. (Previously presented) The method of claim 76, wherein the viscosity is from about 2 to about *5* centipoise.

87. (Currently amended) A method of causing no irritation at the site of injection upon injection of an injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the

dispersion being capable of inhibiting the growth of microorganisms and consisting essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, water, and an aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents.

88. (Previously presented) The method of claim 87, where the propofol and diluent are present in a ratio of about 1:4 to about 1:0.1 of propofol to diluent.

89. (Previously presented) The method of claim 87, where the propofol and amphiphilic agent are present in a ratio of about 1:0.8 to about 1:2.5 of propofol to amphiphilic agent.

90. (Previously presented) The method of claim 87 that has a viscosity of from about 0.8 to about 15 centipoise.

91. (Previously presented) The method of claim 87, wherein the propofol-soluble diluent is selected from the group consisting of a pharmaceutically acceptable saturated fatty acid triglyceride, a pharmaceutically acceptable unsaturated fatty acid triglyceride, and mixtures thereof.

92. (Previously presented) The method of claim 87, wherein the propofol-soluble diluent is selected from the group consisting of pharmaceutically acceptable esters of medium chain fatty acids, pharmaceutically acceptable esters of long chain fatty acids, pharmaceutically acceptable triglycerides of medium chain fatty acids, and mixtures thereof.

93. (Previously presented) The method of claim 87, wherein the propofol-soluble diluent is selected from the group consisting of isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, squalane, alpha-tocopherol, and mixtures thereof.

94. (Previously presented) The method of claim 87, wherein the propofol-soluble diluent is a mixture of medium-chain triglyceride and vegetable oil.

95. (Previously presented) The method of claim 94, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

96. (Previously presented) The method of claim 87, which contains about 2% to about 10% of propofol.

97. (Previously presented) The method of claim 87, wherein the surface stabilizing amphiphilic agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

98. (Previously presented) The method of claim 87, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of charged phospholipid of natural sources, uncharged phospholipid of natural sources, hydrogenated lecithin, a synthetic phospholipid, a poloxamer, a poloxamine, a polyoxyethylene sorbitan ester, and mixtures thereof

99. (Currently amended) The method of claim 87, wherein the surface stabilizing amphiphilic agent is a combination of cholesterol and one or more charged or uncharged ~~phospholipid~~ phospholipids of natural sources, hydrogenated lecithin, or synthetic phospholipids.

100. (Previously presented) The method of claim 87, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of 1,2-dimyristoyl-sn-glycero-3-phosphatidylcholine, 1,2-dimyristoyl-sn-glycero-3-[phospho-rac-(1 -glycerol)], egg lecithin, egg phosphatidylcholine, soy phosphatidylcholine, saturated soy phosphatidylcholine, soy lecithin, dimyristoylphosphatidylcholine, and dimyristoylphosphatidylglycerol.

101. (Previously presented) The method of claim 87, wherein the dispersion elicits an anesthetic effect in a warm-blooded animal and human subject upon intravenous administration.

102. (Previously presented) The method of claim 87, wherein the tonicity modifier is selected from the group consisting of sucrose, dextrose, trehalose, mannitol, lactose, glycerol, and mixtures thereof.

103. (Previously presented) The method of claim 87, wherein the dispersion is isotonic with blood.

104. (Previously presented) The method of claim 87, wherein the dispersion is suitable for intravenous injection.

105. (Currently amended) The method of claim 87, wherein the dispersion contains a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier in an amount sufficient to provide an osmolality of about 250 to about 700 milliosmolal.

106. (Previously presented) The method of claim 105, wherein the osmolality is about 300 to about 500 milliosmolal.

107. (Previously presented) The method of claim 87, wherein the dispersion has a viscosity from about 2 to about 5 centipoise.

108. (Previously presented) The method of claim 36, wherein inducing anesthesia comprises producing and maintaining at least one of ambulatory anesthesia, neurosurgical anesthesia, pediatric anesthesia, monitored anesthetic care, intensive care sedation, chronic sedation, general anesthesia, low dose sedation, and long-term sedation.

109. (Currently amended) A method of inducing anesthesia or sedation, comprising administering to a subject in need of same an anesthetic-inducing amount of a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) propofol in an amount from about 1% to about 15% by weight of the dispersion;

(b) a propofol-soluble diluent in an amount from about 1% to about 8% by weight of the dispersion;

(c) a surface stabilizing amphiphilic agent in an amount from about 0.5% to about 5% by weight of the dispersion;

(d) a pharmaceutically acceptable water-soluble polyhydroxy additive in the dispersion's aqueous phase; and

(e) water;

~~(f)~~ provided the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5 and the composition has a viscosity of about 0.8 to about 15 centipoise;

wherein the dispersion prevents microbial growth of no more than 0.5 log increase from the initial inoculum, of any one of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans,* and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of the microbe is added to an aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range of 20-25°C, whereafter said aliquot is incubated at 20-25°C and tested for viability of the microbe in the inoculated dispersion as determined by counting the colonies of the microbe after 24 hours, 48 hours, and 7 days; and

wherein the dispersion results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.

110. (Currently amended) A method of inducing anesthesia or sedation, comprising administering to a subject in need of same an anesthetic-inducing amount of a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) propofol in an amount of about 2% by weight of the dispersion;

(b) one or more [a] medium-chain ~~triglyceride~~ triglycerides in an amount of 4% by weight of the dispersion;

(c) egg lecithin in an amount of 1.6% by weight of the dispersion;

(d) dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion;

(e) mannitol in the dispersion's aqueous phase in an amount of 5.5% by weight of the dispersion; and

(f) water.

111. (Canceled)

112. (Currently amended) The method of claim 110, wherein the one or more medium-chain triglycerides are ~~triglyceride is~~ of synthetic or natural origin.

113. (Previously presented) The method of claim 110, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

114. (Previously presented) The method of claim 110, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

115. (Previously presented) The method of claim 113, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

116. (Previously presented) The method of claim 110, wherein the dispersion is steam sterilizable.

117. (Currently amended) A method of inducing anesthesia or sedation, comprising administering to a subject in need of same an anesthetic-inducing amount of an injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;

[a] one or more medium-chain ~~triglyceride~~ triglycerides in an amount of 4% by weight of the dispersion;

egg lecithin in an amount of 1.6 % by weight of the dispersion;

dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and

mannitol in [its] the dispersion's aqueous phase in an amount of 5.5% by weight of the dispersion;

wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

118. (Canceled)

119. (Currently amended) The method of claim 117, wherein the one or more medium chain triglycerides are ~~triglyceride is~~ of synthetic or natural origin.

120. (Previously presented) The method of claim 117, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

121. (Previously presented) The method of claim 117, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

122. (Previously presented) The method of claim 120, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

123. (Previously presented) The method of claim 117, wherein the dispersion is steam sterilizable.